In the United States Court of Federal Claims

No. 19-503
(Filed Under Seal: October 10, 2024)[*]
(Reissued: November 12, 2024)

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TRENTON GOODWIN,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Kirk "Tripp" Otto, Attorney, Rawls Law Group, of Richmond, VA, for Petitioner.

Emilie. F. Williams, Trial Attorney, Torts Branch, Civil Division, U.S. Department of Justice, of Washington, D.C., for Respondent.

MEMORANDUM OPINION AND ORDER

SOMERS, Judge.

In both legal and mathematical analysis, a conclusion alone does not suffice. Rather, in both fields, one must reason to his or her result. This is especially the case for decisions that must be reviewed to determine whether they are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Much like trying to grade a math student's exam when no work has been shown, meaningful judicial review under this standard is nearly impossible when the decision to be examined contains insufficient reasoning and even less discussion of the facts that support that reasoning. Here, Petitioner, Trenton Goodwin, has asked the Court to review the decision of the special master to deny him compensation under the National Vaccine Injury Compensation Program ("Vaccine Act"). *See* ECF No. 72. Under the Vaccine Act, upon the filing of a motion for review, a decision of a special master is reviewed by this Court to ensure

[*] On October 10, 2024, the Court issued this opinion and order under seal in accordance with Rule 18(b) of the Vaccine Rules (Appendix B) of the U.S. Court of Federal Claims. The Court provided the parties 14 days to proposed redactions. The parties did not propose any redactions, and, accordingly, the Court reissues this opinion in its original form with a few minor stylistic and typographical corrections.

that it is not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." *See* 42 U.S.C. § 300aa-12(e)(2). As explained below, the Court finds that the special master's decision did not adequately explain why Petitioner's claim was denied, and it remands the case back to the special master for further proceedings.

BACKGROUND

On March 22, 2018, Petitioner, then a minor, received a human papillomavirus ("HPV") vaccination as part of a well-child visit. ECF No. 72-1 at 3; *Goodwin v. Sec'y of Health & Hum. Servs*., No. 19-503V, 2024 WL 2033563 at *1 (Fed. Cl. Apr. 16, 2024). He then exhibited assorted symptoms, including mottled extremities, resulting in an emergency room visit on May 30, 2018, followed by hospitalization. *See Goodwin*, 2024 WL 2033563 at *1. Petitioner claims that the HPV vaccine caused him to develop transverse myelitis. *Id.* The neurologists for both parties agreed that the appropriate diagnosis of Petitioner's condition is transverse myelitis, which first manifested on May 30, 2018. *Id.* As the special master explained in his decision, and as both parties agreed, the interval between the date of vaccination and the onset of symptoms was 68 days. *Id.*

On April 4, 2019, a petition was filed by Petitioner's mother on his behalf for compensation under the Vaccine Act, alleging that the HPV vaccine was the cause-in-fact of his transverse myelitis. *Id.* Once expert reports were filed, the special master concluded that the primary question was whether prong three of the test set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005), had been satisfied. *Goodwin*, 2024 WL 2033563 at *2. Therefore, the special master ordered the parties to file briefs only regarding the issue of timing. ECF No. 58 at 1 ("The parties agreed to brief the issue of timing before addressing theory and logical sequence of cause and effect. Accordingly, the parties are ORDERED to file briefs regarding timing."). After briefing and without oral argument, the special master concluded that Petitioner "failed to show the latency between the vaccination and the onset of his transverse myelitis is compatible with a finding that the vaccination caused the transverse myelitis." *Goodwin*, 2024 WL 2033563 at *1. In other words, the special master rejected the petition because he determined Petitioner failed to satisfy *Althen* prong three due to the length of time that elapsed between the administration of the vaccine and the injury.

On May 16, 2024, Petitioner filed a motion for review of the special master's decision. ECF No. 72. In his motion, Petitioner asserts that the special master: 1) "erred by applying incorrect legal standards in assessing Petitioner's evidence of a proximate temporal relationship between vaccination and injury"; and 2) "erred in [his] analysis of Respondent's expert reports by concluding that some studies demonstrated a shorter window of plausible Transverse Myelitis onset, when those studies did not address this question." *Id.* at 1. The Court held oral argument on Petitioner's motion on July 24, 2024.

DISCUSSION

A. Legal Standard

Under the Vaccine Act, judges of this Court review decisions issued by Vaccine Act special masters upon a petitioner's filing of a motion for review. 42 U.S.C. § 300aa-12(e)(1). As prescribed by the Act, in reviewing the decision of a special master, the Court may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

Id. § 300aa-12(e)(2). In other words, "[u]nder the Vaccine Act, the Court of Federal Claims reviews [a special master's] decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.'" *Markovich v. Sec'y of Health & Hum. Servs.*, 477 F.3d 1353, 1355–56 (Fed. Cir. 2007) (quoting 42 U.S.C. § 300aa-12(e)(2)(B)). The Federal Circuit has indicated that:

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.

Munn v. Sec'y of Health & Hum. Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

Generally, "if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.'" *Hibbard v. Sec'y of Health & Hum. Servs.*, 698 F.3d 1355, 1363 (Fed. Cir. 2012) (quoting *Hines v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)). Therefore, "[t]he court's inquiry . . . must . . . focus on whether the Special Master examined the 'relevant data' and articulated a 'satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" *Dixon v. Sec'y of Health & Hum. Servs.*, 61 Fed. Cl. 1, 8 (2004) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

Here, Petitioner's asserted injury—transverse myelitis allegedly caused by the HPV vaccine—is a "non-table" injury. Accordingly, to prove actual causation by a preponderance of the evidence, Petitioner was required to demonstrate: "(1) a medical theory causally connecting

the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. In this petition for review, only the third *Althen* prong is at issue, which requires a petitioner to prove a "medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury." *Id.* at 1281. Specifically, a petitioner needs to submit "proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The third *Althen* prong closely links with the first prong because the acceptable timeframe must coincide with a petitioner's theory of how a particular vaccine can cause the injury. *Id.* In practice, the third *Althen* prong can be broken down into two steps: (1) "establish the timeframe for which it is medically acceptable to infer causation, that is, the timeframe in which symptoms would be expected to arise if the [disorder] was caused by the vaccination"; and (2) "show that the onset of [the disorder] occurred during this causation period." *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011).

B. Analysis

As mentioned above, in reviewing a special master's decision, Congress has instructed the Court to "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B). This familiar standard of review is borrowed from the Administrative Procedure Act. *Compare id. with* 5 U.S.C. § 706(2)(A). As "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change," *Lorillard v. Pons*, 434 U.S. 575, 580 (1978), this Court employs general administrative law principles in applying the arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law standard to its review of the decisions of vaccine special masters, *see, e.g.*, *Hines ex rel. Sevier v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1527–28 (Fed. Cir. 1991) (applying several Supreme Court and federal appellate court administrative law decisions to define the arbitrary and capricious standard under the Vaccine Act).

With this principle in mind, it becomes quickly apparent that the special master's decision in this case does not offer a reasoned basis for his conclusions sufficient for this Court to review the decision on the grounds raised by Petitioner. Put differently, the special master's decision does not demonstrate that his conclusions were "the product of reasoned decision making" as his decision does not provide enough reasoning to show the Court that he "examine[d] the relevant data," and he did not "articulate a satisfactory explanation for [his] action including a 'rational connection between the facts found and the choice made.'" *State Farm*, 463 U.S. at 52, 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)); *accord Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998) ("Not only must [the] decreed result be within the scope of [] lawful authority, but the process by which it reaches that result must be logical and rational."). Thus, "conclusory statements alone are insufficient and, instead, the finding must be supported by a reasoned explanation [nor is it] adequate to summarize and reject arguments without explaining why . . . ." *In re NuVasive, Inc.*, 842 F.3d 1376, 1383 (Fed. Cir. 2016) (rejecting a decision of the PTAB for insufficient

reasoning) (internal quotations omitted). Rather, a decision-maker must "provide a reasoned explanation for its action." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1916 (2020). As the Federal Circuit has explained, "[f]or judicial review to be meaningfully achieved within the[] strictures [of APA review], the [decision-maker] must present a full and reasoned explanation of its decision. The [decision-maker] must set forth its findings and the grounds thereof, as supported by the [] record, and explain its application of the law to the found facts." *In re Sang Su Lee*, 277 F.3d 1338, 1342 (Fed. Cir. 2002). In short, "[t]his standard requires that the [decision-maker] not only have reached a sound decision, but have articulated the reasons for that decision." *Id.*

To begin, the special master's discussion of the facts of the case is a mere ten sentences long, only two of which arguably relate to *Althen* prong three, the ground on which the special master rested his decision. *Goodwin*, 2024 WL 2033563 at *1. While lengthy recitation of the facts of a case is not always required, the truncated facts section likely contributed to the overall lack of explanation of the reasoning behind the special master's decision. In the section of the special master's decision labeled "Analysis," the special master begins by stating that "[t]he analysis focuses on Dr. Steinman because [Petitioner] bears the burden to prove his case with preponderate evidence." *Id.* at *3. But the analysis does not appear to focus on Dr. Steinman. In fact, there are just two sentences focused solely on Dr. Steinman's opinion: "Dr. Steinman relies upon the Menge case series. Dr. Steinman does not unpack the steps of his theory to explain how the process of molecular mimicry could culminate in the development of transverse myelitis sixty-eight days later." *Id.* (citations omitted). Missing is any explanation of what Dr. Steinman's theory is (other than to say it is based on molecular mimicry) or how it is that he did not "unpack" his steps. This leaves the reviewing Court to ask what exactly Dr. Steinman's theory is? What were the steps of his theory? How did he not "unpack" those steps? In short, these two conclusory sentences regarding Dr. Steinman and his expert opinion do not give the Court a reasoned basis from which it can review the special master's determination that Dr. Steinman did not explain his opinion regarding *Althen* prong three. To be fair, there is some additional discussion of Dr. Steinman's theory as it relates to the Menge case series. However, the special master outlined the evidence he reviewed in reaching his determination and that outline indicates that the Menge case series is a separate piece of evidence, which was considered apart from Dr. Steinman's expert opinion. With regard to Dr. Steinman in particular, the special master does not explain what Dr. Steinman's theory is, nor does he explain what is wrong with this theory. Rather, the special master simply states the conclusion that Dr. Steinman did not "unpack" his theory sufficiently.

Moving on to the Menge case series, the special master devotes five sentences to opine that Dr. Steinman's opinion was incorrect in re-diagnosing two of the cases in the Menge case series. *Id.* at *4. The special master uses vague language to describe his reasoning for discarding Dr. Steinman's re-diagnosis of the Menge cases, such as that "Dr. Steinman's re-diagnosis seems to stretch his abilities." *Id.* It is unclear what abilities Dr. Steinman was stretching, whether the re-diagnosis was actually beyond Dr. Steinman's abilities, and what, if any, flaws there were in Dr. Steinman's re-diagnosis. The special master answers none of these questions. Instead, the special master simply dismissed Dr. Steinman's re-diagnosis opinion, stating in a conclusory fashion that Dr. Steinman has "not persuasively shown that the doctors treating these two patients erred in their diagnoses." *Id.*

The special master then addresses Petitioner's other Menge-case-series-based argument: that since both neuromyelitis optica and transverse myelitis are demyelinating diseases, information about the onset of neuromyelitis optica can be used to determine whether transverse myelitis may fit within the appropriate timeframe. *Id*. ("A more critical question is whether evidence about condition A (for example NMO) can inform an analysis about condition B (for example transverse myelitis)."). The special master was correct in determining that this was a critical question. Unfortunately, the special master fails to answer the question. He explains that "special masters have often based findings regarding the appropriate temporal relationship on studies involving a disease that is different from the disease affecting a vaccinee" but that the ultimate answer "depends upon a variety of factors." *Id.* The only factor mentioned by the special master, however, is "that the Menge case series contains, at best, a single case report in which a person may have developed *transverse myelitis*." *Id.* (emphasis added). But developing *transverse myelitis* was not the question the special master said he was answering in this part of his decision. Rather the question, according to the special master, was whether evidence regarding developing *neuromyelitis optica* can be extrapolated to inform an analysis about the development of *transverse myelitis*. *Id.* In what seems to be a trend, it does not appear that the special master addressed this question.

Closely related to the Menge case series, the special master next discusses an article by the Agmon-Levin group that Petitioner "puts forward . . . that Dr. Steinman did not cite." *Id.* The special master questions whether the Agmon-Levin case series supports the proposition that "a neurologic disease, which [the Menge authors] call NMO and Dr. Steinman calls transverse myelitis, was caused by an HPV vaccination given five months earlier." *Id.* at *5. But it once again does not appear that the special master answers this question. The special master cites the respondent's expert's use of the Agmon-Levin case series for the proposition that 73% of transverse myelitis cases within the study occurred within 30 days of vaccination, and Petitioner's use of the study for the other side of the coin that 27% of transverse myelitis cases occurred more than 30 days post vaccination. *Id.* at *4. He then dismisses the study by calling it "essentially a case series which carries little value." *Id.* at *5. However, he immediately follows this observation by stating that both the Menge and the Agmon-Levin authors' suggestions, that a neurological disease was caused by an HPV vaccination, "is entitled to some consideration." *Id.* But what "consideration" this suggestion is entitled to is unclear. The only conclusion given by the special master is that "these pieces of evidence must be weighed against other evidence." *Id.* Without answering this question, he then proceeds to the second part of the decision, in which he weighs the "larger studies" presented by the respondent. *Id.* To weigh, though, one needs to know what weight is on each side of the scale, and here, the special master provides a muddled explanation at best as to what weight he is putting on the Menge and Agmon-Levin side of the scale.

The special master begins his discussion of the "larger" Pidcock, De Goede, and Baxter studies by noting that one of the respondent's experts opined that a "42-day risk period is widely used to determine temporal association between vaccination and an adverse event. This risk window is based upon many epidemiologic studies with infections and/or vaccinations." *Id.* (quoting Exhibit CCC at 4). He then asserts that the "larger studies, which were submitted into the record, are consistent with [Respondent's expert's] opinion." *Id.* The first study discussed

by the special master is Pidcock. *Id.* Unfortunately, nowhere in the special master's discussion of Pidcock does he explain how Pidcock supports the respondent's expert's opinion, which is supposedly the reason for the discussion of the Pidcock study in the first place. Regarding the Pidcock study, the special master summarizes that the study "found about half the cases experienced an infectious disease within about three weeks of the onset . . . [and that] about one-quarter of the people who developed transverse myelitis received an immunization or allergy shot within about three weeks before the onset of neurologic symptoms." *Id.* (citation omitted). But what about the other half of the cases that experienced an infectious disease after three weeks and the other three-quarters who developed transverse myelitis more than three weeks post-vaccination? And, more importantly, what about the "42-day risk period"? Forty-two days is six weeks, yet the special master only discussed metrics involving a three-week timeframe.

The special master then identifies that Petitioner's critique of the Pidcock study was that that the Pidcock researchers only included children who developed transverse myelitis within thirty days of vaccination. *Id.* The special master dismisses this critique by saying "[t]his statement is not accurate. A majority (about 72%) of the subjects in the Pidcock article did not receive a vaccination in the three weeks preceding the onset of neurologic symptoms." *Id.* This response is a non sequitur to Petitioner's critique. Even if all of the subjects in the Pidcock study did not receive a vaccination in the three weeks prior to neurological symptom onset, all of them still could have received a vaccination in the fourth week prior to neurological symptom onset, which would be within the 30-day window to which Petitioner referenced.

Next, the special master turns to the De Goede study, devoting just one paragraph to his analysis of that study, quoted here in its entirety:

> This group of researchers surveyed all pediatric neurologists in the United Kingdom to report incidents of myopathy in children less than sixteen years old. Through this process, they identified 41 cases of acute transverse myelitis. Like the Pidcock group, De Goede and colleagues reported on the children's presentation, MRI scans, treatments, and outcomes. For presentation, "27 cases had a preceding infectious illness or vaccination less than three weeks prior to presentation."

Id. (citations omitted). The Court is at a loss as to the special master's conclusion regarding this study. The closest this paragraph has to a conclusion is the last sentence: "[f]or presentation, 27 cases had a preceding infectious illness or vaccination less than three weeks prior to presentation." *Id.* (internal quotation marks omitted). Does this help Respondent? The Petitioner? Does it support the "42-day risk period" referenced above? What happened in the 14 cases not covered by the special master's conclusion?

With regard to the final study referenced by the special master—the Baxter study—the special master states that the Baxter study "makes explicit what is implicit in Pidcock and De Goede." *Id.* at *6. Presumably, the special master was attempting to say that the cases in the Baxter study support the "42-day risk period" pointed to by the respondent's expert because that is supposedly why the special master examined these three studies. However, the entirety of the special master's interpretation of Baxter can be summed up as reasoning that, since the Baxter researchers used a group who developed transverse myelitis between 43 days and 9 months as

the control group for their study, the Baxter researchers must have determined that beyond 42 days a vaccination could not be the cause of transverse myelitis. Beyond lacking citation, it is not clear from the special master's conclusion that this is in fact what the Baxter researchers concluded or whether this conclusion is accurate. As Petitioner points out in his petition for review, the Baxter study "did not investigate the question relevant to this claim for compensation, whether a timeframe of 68 days between vaccination and onset of [transverse myelitis] is medically acceptable." ECF No. 72-1 at 18.[1] If the special master is going to draw this conclusion from the Baxter study, more explanation is needed as to the validity of the conclusion and whether this is the special master's conclusion or the conclusion of the Baxter study.

Finally, the special master discusses whether the vaccine program in general permits an onset in a similar timeframe post-vaccination administration. *Goodwin*, 2024 WL 2033563 at *6. He references several other vaccine opinions endorsing limiting onset to within 42 days, and then contrasts that with other special masters who have "also broadened the time period beyond 42 days." *Id.* at *7. He then apparently reaches the conclusion that Petitioner's onset timeframe must be unacceptable because "this broadening is not limitless" and that the "third prong of *Althen* must have some meaning." *Id.* While these are certainly true statements, citing several cases involving different conditions or different vaccines is not the most persuasive evidence that Petitioner's alleged onset fails the third prong of the *Althen* test. These paragraphs discussing other onset timeframe cases cannot save a decision otherwise lacking a reasoned basis.

Although the result the special master reached in this case may ultimately be correct, the Court simply cannot sustain the result based on the reasoning given. For all the reasons discussed above, the Court must remand this matter to the special master so that he can articulate a basis for his decision that the Court can consider under the prescribed standard if either Petitioner or the respondent is dissatisfied with the result on remand.

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[1] Petitioner also observes that:

> The Baxter study authors concede they chose a 5 to 28 day window, and a 2 to 42 day window, based on prior studies and opinion. Exh. H, Baxter et al., *Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis*, 63 Clin. Infect. Disease 1456, 1459 (2016). The Baxter study authors explained in their limitations section, "The method depends on selection of an appropriate risk (exposure) interval, so if the interval is misspecified, an increased risk could have been missed." *Id.* at 1461. The results of the Baxter study included 81 cases, 67 of which had a vaccination within 9 months prior to onset, but only one within the 42-day window. *Id.* at 1460. In other words, *66 of the cases had a vaccination within nine months but were outside of the pre-selected window used by the study authors*. In summary, any contribution from the Baxter study would be that the authors, before the study started, understood medical opinion to accept a shorter timeframe between vaccination and onset of [transverse myelitis] as typical.

ECF No. 72-1 at 18.

CONCLUSION

For the reasons stated above, the Court finds that the special master's decision does not permit it to meaningfully review the errors alleged by Petitioner. In light of this, Petitioner's motion for review is **GRANTED**, and the special master's decision (ECF No. 69) is **VACATED**. The case is **REMANDED** to the special master for further proceedings consistent with this opinion. The special master shall review the record, order any necessary supplemental briefing from the parties, and issue a new entitlement decision within **ninety days** of this decision. *See* 42 U.S.C. § 300aa-12(e)(2); RCFC App. B, Rule 28(b).

IT IS SO ORDERED.

s/ Zachary N. Somers
ZACHARY N. SOMERS
Judge